

REMARKS

Claims 11, 14 and 21-33 were pending in the application. Claims 11 and 27 have been amended. Claims 26 and 33 have been canceled. Accordingly, upon entry of the amendments presented herein, claims 11, 14, 21-25, 27-32 will remain pending in the application.

Support for the amendments to claims 11 and 27 can be found throughout the specification as originally filed. Specifically, support for the amendments to claims 11 and 27 can be found at least, for example, at page 4, lines 15-31; page 5, lines 15-18 and lines 21-22; page 31, line 1 through page 34, line 5; page 37, line 5 through page 41, line 22 of the specification. Accordingly, no new matter has been added to the application by way of these amendments.

The foregoing claim amendments have been made solely for the purpose of expediting prosecution of the present application and should in no way be construed as an acquiescence to any of the Examiner's rejections in this or in any former Office Action issued in the present application. Applicants reserve the right to pursue the subject matter of the present claims prior to being amended herein in this application or in another related application.

In view of the foregoing claim amendments and the arguments set forth below, Applicants respectfully submit that the claims are now in condition for allowance.

Rejection of Claims 11, 14, and 21-33***Under 35 U.S.C. § 112, First Paragraph – Enablement***

The Examiner has rejected claims 11, 14 and 21-33 under 35 U.S.C. § 112, first paragraph, because, according to the Examiner, "the specification, while being enabling for treating cancer or hypercholesterolemia, does not reasonably provide enablement for prevention of these disorders." The Examiner alleges that for the claimed invention to prevent a cancer or hypercholesterolemia it must do so in "each and every instance" and "for all potential causes of cancer or hypercholesterolemia."

Applicants respectfully disagree. However to expedite prosecution, Applicants have amended claims 11 and 27, thereby obviating the rejection. Claims 11 and 27, as amended, are drawn to compositions suitable for treating or *reducing the risk of acquiring* a cancer or hypercholesterolemia. Support for the amendments to claims 11 and 27 can be found at least, for example, at page 4, lines 15-31; page 5, lines 15-18 and lines 21-22; page 31, line 1 through page 34, line 5; page 37, line 5 through page 41, line 22 of the specification. Specifically, Applicants' specification teaches that administration of the claimed composition *reduced* the incidence of tumor metastasis in a test animal with cancer (see Example 2, line 1, page 31 through page 34, line 4). Furthermore, Applicants teach that administration of the claimed composition to an animal on a casein diet resulted "in a significant *reduction* of undesirable

LDL cholesterol levels, a significant increase of desirable HDL cholesterol levels, and an improvement (*i.e.*, a significant decrease) in the LDL/HDL cholesterol ratio" [*emphasis added*] (see Table 11, page 41; and Example 4, page 40, line 24 through page 41, line 1).

Thus, based on the teachings in the specification the ordinarily skilled artisan would be able to make and use the claimed invention using only routine experimentation. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 11, 14 and 21-33 under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 11, 14, and 21-33
Under 35 U.S.C. § 112, Second Paragraph – Indefiniteness

The Examiner has rejected claims 11, 14 and 21-33 under 35 U.S.C. § 112, first paragraph, as being indefinite based on the term "enriched." Specifically, the Examiner is of the opinion that "[i]t is unclear what levels of cinnamic acid must be present in the cranberry extract in order for the extract to be considered 'enriched'".

Applicants respectfully disagree and maintain that the term "enriched" is sufficiently clear and definite based on Applicants' specification and the art-recognized, ordinary meaning of this term. Moreover, based on the specification and the art-recognized meaning of the term "enriched," the term would be understood to mean any level of increase in a component as compared to, for example, the level of the component in a native fruit. As discussed in the specification, Applicants teach cranberry extracts which are rich in therapeutically beneficial compounds. For example, the cranberry extracts of the invention are described in the specification as being "**enriched** for a number of health promoting compounds" (page 8, lines 4-7) and containing "a remarkably **high concentration** of particularly desirable components (*e.g.*, an anthocyanin, a phenolic acid, a proanthocyanidin)" (page 11, lines 1-5) [*emphasis added*]. Applicants also teach methods for preparing enriched cranberry fruit extracts (page 10, lines 9-11; and page 42, lines 12-14), which would make the meaning of this term clear and definite, as well as methods for isolating the claimed compounds from cranberries (page 15, line 29 through page 17, line 22), and methods to further "**scale up**," *i.e.*, **enrich** or concentrate, these isolated compounds from cranberries (page 16, line 23 through page 17, line 22) [*emphasis added*].

For example, in certain embodiments, Applicants teach that the extracts of the invention comprise an "anthocyanin content [that] is typically 30% or greater of that present in native cranberry fruit, [a] phenolic acid content [that] is typically 8% or greater of that present in native cranberry fruit, [and/or a] proanthocyanidin content [that] is typically 60% or greater of that present in native cranberry fruit" (page 6, lines 9-12) [*emphasis added*]. As discussed in the specification at page 6, lines 15-20, "**phenolic** compounds of the invention include, *e.g.*, para-coumaric acid, caffeic acid, chlorogenic acid, ferulic acid, protocatechuic acid, **cinnamic acid**,

benzoic acid, gallic acid, para-hydroxybenzoic acid, or a combination thereof" [*emphasis added*]. As such, it would be readily apparent to one of ordinary skill in the art as to the meaning of the claimed composition as being "enriched" for one of the foregoing compounds discussed, including phenolic compounds such as cinnamic acid.

For at least the foregoing reasons, Applicants respectfully request withdrawal of the rejection of claims 11, 14, 21-25 and 27-32 under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 11, 14, and 21-33

Under 35 U.S.C. § 102(b) – Anticipation

The Examiner has rejected claims 11, 14 and 21-33 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No.: 5,320,861. The Examiner acknowledges that U.S. Patent No.: 5,320,861 "does not specifically teach that the extract is enriched in cinnamic acid" and "does not teach that the composition has the same effects on the body as those claimed by applicant." Notwithstanding, the Examiner argues that U.S. Patent No.: 5,320,861 "contains the desired levels of the compounds and is an extract used as applicant's composition" and concludes that the referenced composition would inherently have the same function as the claimed invention.

Applicants respectfully traverse the Examiner's rejections for at least the following reasons. Claim 11, as amended, and claims dependent therefrom, are drawn to a composition suitable for administering to a subject comprising a cranberry extract ***enriched for a compound*** selected from the group consisting of a phenolic acid, flavanoid, fiber, omega-3-fatty acid, tocochromanol, triterpenoid, ellagic acid, and combinations thereof, in a form suitable and in an amount effective to treat or reduce the risk of acquiring a cancer or hypercholesterolemia. Claim 27, as amended, and claims dependent therefrom, are drawn to a cranberry extract ***enriched for one or more compounds*** in an amount effective to treat or reduce the risk of acquiring a cancer or hypercholesterolemia.

As the Examiner is aware, for a prior art reference to anticipate the claimed invention, the reference must teach each and every element of the claimed invention. *Lewmar Marine v. Barent*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987). Contrary to the Examiner's assertion, U.S. Patent No.: 5,320,861 does not disclose compositions which are ***enriched for one or more compounds***, as is required by the present claims. U.S. Patent No.: 5,320,861 teaches methods for extracting fruit juices (*e.g.*, cranberry juice) from raw fruits, in particular, the use of decharacterized cranberries in making fruit juice. These juice extracts are not enriched for any particular compound, as they are merely taken directly from native fruit. In contrast, the presently claimed compositions are "***enriched over the levels of these compounds found in decharacterized cranberries prepared by conventional methods*** (see Table 12)" (page 42, lines 14-25) [*emphasis added*]. Indeed, the cranberry extracts of the invention are "***enriched*** for a

number of health promoting compounds" (page 8, lines 4-7) and contain "a remarkably **high concentration** of particularly desirable components (e.g., an anthocyanin, a phenolic acid, a proanthocyanidin)" (page 11, lines 1-5) [*emphasis added*]. These concentrations do not exist in nature. For example, the cranberry extracts of the invention are described as being enriched for "anthocyanin content [that] is typically 30% or greater of that present in native cranberry fruit," phenolic acid content [that] is typically 8% or greater of that present in native cranberry fruit," and "proanthocyanidin content [that] is typically 60% or greater of that present in native cranberry fruit" (page 6, lines 9-12) [*emphasis added*]. Accordingly, U.S. Patent No.: 5,320,861 does not teach a cranberry extract **enriched** for the recited compounds, as is presently claimed.

Thus, because U.S. Patent No.: 5,320,861 fails to teach or suggest each and every limitation of the claimed invention, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

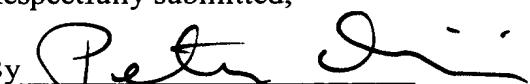
CONCLUSION

In view of the foregoing, entry of the amendments and remarks herein, reconsideration and withdrawal of all rejections, and allowance of the instant application with all pending claims are respectfully solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

An extension of time and appropriate fee is being filed herewith. If any additional fees are due, please charge our Deposit Account No. 12-0080, under Order No. OSJ-002RCE2 from which the undersigned is authorized to draw.

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Respectfully submitted,

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